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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,264	03/23/2001	Andrey A. Boukharov	38-21(51237)G	8785

28381 7590 11/05/2003

ARNOLD & PORTER  
IP DOCKETING DEPARTMENT; RM 1126(b)  
555 12TH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/815,264	BOUKHAROV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,8-11,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-11,38-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### ***Election/Restrictions***

Applicant's continued traversal of the restriction requirement is acknowledged. As the withdrawn claims have been cancelled, the arguments are now moot. Upon allowance of the elected claims, rejoinder will be considered.

An action on the merits of pending claims 1-5, 8-11 and 38-39 follows.

### ***Specification***

Applicant is thanked for kindly providing another copy of the CD-ROM containing Tables in response to the examiner's request. The Tables and data on the new CD-ROM are clear and comprehensible.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not repeated herein are hereby withdrawn.

### ***Claim Rejections - 35 USC § 101***

Claims 1-5, 8-11, and 38-39 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the asserted utility for the inventive sequences as a promoter or regulatory element, while specific, is not a substantial utility for elected SEQ ID NO: 1. Further characterization of the claimed subject matter would be required to identify or

reasonably confirm a “real world” use for the reasons set forth below. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Applicant's arguments filed 8/7/03 have been fully considered but they are not persuasive. Applicant argues that as the inventive sequences may be used as promoter of other regulatory region, it provides a practical and substantial benefit to the public. The previous office action never stated that a promoter or regulatory sequence does NOT have a utility under 35 USC 101, but stated that SEQ ID NO: 1 has not been shown to BE a promoter or other regulatory element. As previously set forth, while a utility as a promoter may be a specific one (i.e. it is not a utility that can be applied to all nucleic acids), this utility has not been established as one which applies to elected SEQ ID NO: 1. If SEQ ID NO: 1 does actually have promoter or other regulatory activity, then this utility would be specific for SEQ ID NO: 1 and the claims have utility. This is not the case for the instant claims, however, as it has not been established that SEQ ID NO: 1 is indeed a promoter/regulatory sequence.

The specification discloses, as set forth in the previous office action, that the inventive sequences are regulatory elements, specifically promoters, but does not explicitly identify SEQ ID NO: 1 as a regulatory element or promoter anywhere. The specification sets forth, on page 9, a definition of a promoter, and on page 20, describes the activity of promoter. Nowhere does the specification disclose whether SEQ ID NO: 1 actually is known to have the described activity. The specification further sets forth a prophetic assay, in Example 1, for confirming whether a sequence is indeed a

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regulatory element/promoter. However, applicant has not supplied any evidence or other confirmation to show whether SEQ ID NO: 1 is indeed a promoter or has other regulatory activity. The Office does not have the facilities to run the described assays, therefore, in the absence of any evidence that SEQ ID NO: 1 is indeed a promoter, the claims lack utility based on identification of SEQ ID NO: 1 as a promoter.

Applicant further argues that the instant specification also teaches multiple uses for the claimed nucleic acids; for example, as a marker in genetic mapping, to isolate promoters, to identify polymorphisms, and as a probe or primer. In response, it is noted that these are all uses applicable to any nucleic acid and are not specific, substantial and credible for SEQ ID NO: 1.

With regard to the argument that a sequence need not appear in the prior art to have utility, it is noted that a sequence may have utility under 35 USC if there is a well-established utility for that sequence. If a sequence is not known in the prior art, then it is unlikely to have a well-established utility. In the absence of a well-established utility, a disclosed substantial, specific, and credible utility may meet the provisions of 35 USC 101. The examiner did not intend to imply that a sequence must be known in order to meet the requirement of 35 USC 101, but merely meant to point out that a well-established utility is not known for SEQ ID NO: 1.

As SEQ ID NO: 1 does not have a specific, substantial and credible utility for the reasons set forth above, and for the reasons previously set forth and maintained above, the rejection of claims 1-5 and 8-11 is maintained and claims 38-39 are rejected.

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Claims 1-5, 8-11, and 38-39 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicant's arguments filed 8/7/03 have been fully considered but they are not persuasive. Applicant argues that as the claims have utility, they are enabled. In response, it is noted that the utility rejection is maintained, as set forth above, therefore the enablement rejection is of claims 1-5 and 8-11 is maintained and claims 38-39 are rejected..

### ***Conclusion***

Claims 1-5, 8-11 and 38-39 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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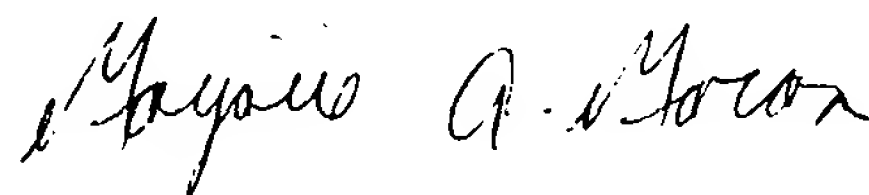
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



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